
WELSH STATUTORY INSTRUMENTS

2020 No. 1073

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

PART 1

Introductory

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

(2) The following provisions come into force on 1 October 2020—

- (a) this Part;
- (b) Parts 2 to 4;
- (c) Parts 9 to 11.

(3) Parts 5 to 8 come into force on 1 October 2021.

(4) These Regulations apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

“the 2006 Act” (*“Deddf 2006”*) means the National Health Service (Wales) Act 2006;

“the 1992 Regulations” (*“Rheoliadau 1992”*) means the National Health Service (Pharmaceutical Services) Regulations 1992(1) as in force immediately before 10 May 2013;

“the 2005 Regulations” (*“Rheoliadau 2005”*) means the National Health Service (Pharmaceutical Services) Regulations 2005(2) as in force immediately before 1 September 2012;

“the 2013 Regulations” (*“Rheoliadau 2013”*) means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013(3) as in force immediately before 1 October 2020;

“additional opening hours” (*“oriau agor ychwanegol”*) is to be construed, as the context requires, in accordance with paragraph 23(11) of Schedule 5 or paragraph 13(10) of Schedule 6, or both;

“advanced electronic signature” (*“llofnod electronig uwch”*) means an electronic signature which meets the following requirements—

- (a) it is uniquely linked to the signatory,

(1) S.I. 1992/662, revoked by S.I. 2013/898 (W. 102).

(2) S.I. 2005/641, revoked by S.I. 2012/1909.

(3) S.I. 2013/898 (W. 102), amended by S.I. 2004/478 (W. 48).

- (b) it is capable of identifying the signatory,
- (c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under the signatory's sole control, and
- (d) it is linked to the data signed in such a way that any subsequent change in the data is detectable;

“APMS” (“*GMDdA*”) means primary medical services provided in accordance with an APMS contract;

“APMS contract” (“*contract GMDdA*”) means an arrangement to provide primary medical services made with a Local Health Board under section 41(2)(b) of the 2006 Act (primary medical services);

“APMS contractor” (“*contractwr GMDdA*”) means a party to an APMS contract, other than a Local Health Board;

“appliance” (“*cyfarpar*”) means an appliance which is included in a list approved by the Welsh Ministers for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);

“appliance use review service” (“*gwasanaeth adolygu defnyddio cyfarpar*”) means arrangements made in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services) for an NHS pharmacist or NHS appliance contractor to review a person's use of any specified appliance;

“appropriate batch issue” (“*swp-ddyroddiad priodol*”) means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

“appropriate non-proprietary name” (“*enw amherchnogol priodol*”) means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;

“bank holiday” (“*gŵyl banc*”) means any day that is specified or proclaimed as a bank holiday in Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(4);

“batch issue” (“*swp-ddyroddiad*”) means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a NHS pharmacist or NHS appliance contractor to receive payment for the provision of repeat dispensing services which is in the required format, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber,
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription,
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided, and
- (d) specifies a number denoting its place in the sequence referred to in paragraph (c);

“Charges Regulations” (“*Rheoliadau Ffioedd*”) means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(5);

“child” (“*plentyn*”) means a person who has not attained the age of 16 years;

“Community Health Council” (“*Cyngor Iechyd Cymuned*”) means a Community Health Council retained or established under section 182 of the 2006 Act (community health councils);

(4) 1971 c. 80.

(5) S.I. 2007/121 (W. 11), amended by S.I. 2013/898 (W. 102).

“conditional inclusion” (“*cynnwys yn amodol*”) means inclusion in a pharmaceutical list or the grant of preliminary consent to be included in a pharmaceutical list subject to conditions imposed under Part 7 of these Regulations;

“contingent removal” (“*dileu yn ddigwyddiadol*”) means removal from a pharmaceutical list contingently, within the meaning of section 108 of the 2006 Act (contingent removal);

“controlled locality” (“*ardal reoledig*”) means an area which a Local Health Board has determined to be rural in accordance with regulation 13 (areas that are controlled localities), which the Welsh Ministers have determined on appeal, in accordance with Parts 1 and 2 of Schedule 4, to be rural or which is a controlled locality by virtue of the operation of regulation 13(1);

“core hours” (“*oriau craidd*”) means the hours during which pharmacy, or appliance contractor, premises must be open by virtue of paragraph 23(1) of Schedule 5, or paragraph 13(1) of Schedule 6;

“dentist” (“*deintydd*”) means a dental practitioner;

“directed services” (“*gwasanaethau cyfeiriedig*”) means additional pharmaceutical services provided in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services);

“director” (“*cyfarwyddwr*”) means—

- (a) a director of a body corporate, or
- (b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

“dispensing doctor” (“*meddyg fferyllol*”) means a doctor who provides pharmaceutical services under arrangements with a Local Health Board made under regulation 26 (arrangements for the provision of pharmaceutical services by doctors);

“dispensing doctor list” (“*rhestr meddygon fferyllol*”) means a list that a Local Health Board is required to prepare and maintain under regulation 11 (preparation and maintenance of dispensing doctor lists);

“doctor” (“*meddy*”) means a registered medical practitioner;

“Drug Tariff” (“*Tariff Cyffuriau*”) has the meaning given to it in regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

“drugs” (“*cyffuriau*”) includes medicines;

“EEA” (“*AEE*”) means the European Economic Area created by the EEA agreement;

“electronic communication” (“*cyfathrebiad electronig*”) has the meaning given in section 15(1) of the Electronic Communications Act 2000⁽⁶⁾ (general interpretation);

“electronic prescription” (“*presgripsiwn electronig*”) means an electronic prescription form or an electronic repeatable prescription;

“electronic prescription form” (“*ffurflen bresgripsiwn electronig*”) means data created in an electronic form for the purpose of ordering a drug or appliance which—

- (a) is signed with a prescriber’s advanced electronic signature,
- (b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service, and
- (c) does not indicate that the drug or appliance ordered may be provided more than once;

⁽⁶⁾ The definition of “*electronic communication*” was amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

“electronic repeatable prescription” (“*presgripsiwn amlroddadwy electronig*”) means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription”;

“electronic signature” (“*llofnod electronig*”) means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;

“electronic signature creation data” (“*data creu llofnod electronig*”) means unique data which is used by the signatory to create an electronic signature;

“employment” (“*cyflogaeth*”) includes unpaid employment and employment under a contract for services;

“equivalent body” (“*corff cyfatebol*”) means the National Health Service Commissioning Board in England, a Health Board in Scotland, a Health and Social Services Board in Northern Ireland or any successor body in England, Scotland or Northern Ireland and, in relation to any time prior to 1 April 2003, a Health Authority in Wales or in relation to any time prior to 1 April 2013 and after 30 September 2002 a Primary Care Trust in England, or in relation to any time prior to 1 October 2002, a Health Authority in England;

“equivalent list” (“*rhestr gyfatebol*”) means a list kept by an equivalent body;

“essential services” (“*gwasanaethau hanfodol*”) for NHS pharmacists means the services specified in paragraph 3 of Schedule 5 and for NHS appliance contractors means the services specified in paragraphs 3 to 12 of Schedule 6;

“ETP service” (“*gwasanaeth TPE*”) means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;

“General Pharmaceutical Council Register” (“*Cofrestr y Cyngor Fferyllol Cyffredinol*”) means the register maintained under article 19 of the Pharmacy Order 2010(7) (establishment, maintenance of and access to the Register);

“GMS contract” (“*contract GMC*”) means a general medical services contract under section 42 of the 2006 Act (general medical services contracts: introductory);

“GMS contractor” (“*contractwr GMC*”) means a party to a GMS contract, other than the Local Health Board;

“GMS Regulations” (“*Rheoliadau GMC*”) means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(8);

“the Health and Care Professions Council register” (“*cofrestr y Cyngor Proffesiynau Iechyd a Gofal*”) means the register established and maintained by the Health and Care Professions Council under article 5 of the Health and Social Work Professions Order 2002(9);

“health care professional” (“*proffesiynolyn gofal iechyd*”) means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Healthcare Professions Act 2002(10);

“independent nurse prescriber” (“*nyrs sy'n rhagnodi'n annibynnol*”) means a person—

(7) S.I. 2010/231.

(8) S.I. 2004/478 (W. 48), amended by S.I. 2004/1017 (W. 114), S.I. 2006/358 (W. 46), S.I. 2006/945 (W. 94), S.I. 2007/121 (W. 11), S.I. 2007/205 (W. 19), S.I. 2008/1329 (W. 138), S.I. 2008/1425 (W. 147), S.I. 2010/729 (W. 70), S.I. 2010/1647 (W. 155), S.I. 2011/704 (W. 108), S.I. 2012/1479, S.I. 2012/1916, S.I. 2012/2404, S.I. 2013/235, S.I. 2013/898 (W. 102), S.I. 2014/1887, S.I. 2014/2291 (W. 226), S.I. 2016/90 (W. 43), S.I. 2016/211 (W. 84), S.I. 2016/481, S.I. 2016/1221 (W. 292). There are other amendments but none are relevant.

(9) S.I. 2002/254, amended by paragraph 2 of Schedule 2 to the Health Care and Associated Professions (Miscellaneous Amendments and Practitioner Psychologists) Order 2009 (S.I. 2009/1182). There are other amendments to the Order but none are relevant.

(10) 2002 c. 17, amended by the Health and Social Care Act 2008 (c. 14) and the Pharmacy Order 2010 (S.I. 2010/231). There are other amendments but none are relevant.

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

“joint discipline committee” (“*cyd-bwyllgor disgyblu*”) has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**11**) (interpretation);

“LHBMS” (“*GMBILF*”) means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act (primary medical services);

“LHBMS practice” (“*practis GMBILF*”) means a practice providing LHBMS;

“licensing or regulatory body” (“*corff trwyddedu neu reoleiddio*”) means any body that licences or regulates any profession of which the person is or has been a member, and includes any body which licences or regulates any such profession in a country other than the United Kingdom;

“list” (“*rhestr*”), unless the context otherwise requires, means a pharmaceutical list or a dispensing doctor list;

“listed premises” (“*mangre restredig*”) means the premises that are included in—

- (a) a pharmaceutical list, or
- (b) a dispensing doctor list pursuant to regulation 11 (preparation and maintenance of dispensing doctor lists);

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a Local Health Board established under section 11 of the 2006 Act (local health boards);

“Local Medical Committee” (“*Pwyllgor Meddygol Lleol*”) means a committee recognised under section 54 of the 2006 Act (local medical committees);

“Local Pharmaceutical Committee” (“*Pwyllgor Fferyllol Lleol*”) means a committee recognised under section 90 of the 2006 Act (local pharmaceutical committees);

“local pharmaceutical services” (“*gwasanaethau fferyllol lleol*”) means services of a kind which may be provided under section 80, or by virtue of section 81, of the 2006 Act, other than practitioner dispensing services, and which are provided under a pilot scheme;

“medical performers list” (“*rhestr cyflawnwyr meddygol*”) means a list of doctors prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004(**12**);

“national disqualification” (“*anghymhwysiad cenedlaethol*”) means—

- (a) a national disqualification as mentioned in section 115(2) and (3) of the 2006 Act (national disqualification),
- (b) a national disqualification as mentioned in section 159(2) and (3) of the National Health Service Act 2006(**13**) (national disqualification),
- (c) any decision in Scotland or Northern Ireland corresponding to a national disqualification under section 115(2) and (3) of the 2006 Act, and
- (d) any other decision that was a national disqualification for the purposes of the 2005 Regulations;

(11) S.I. 1992/664. The definition of “joint discipline committee” was inserted by S.I. 1996/703.

(12) S.I. 2004/1020 (W. 117), amended by S.I. 2006/945 (W. 94).

(13) 2006 c. 41. Section 159 has been amended by S.I. 2010/22 and the Health and Social Care Act 2012 (c. 7).

“NHS appliance contractor” (“*contractwr cyfarpar GIG*”) means a person who is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;

“NHS Business Services Authority” (“*Awdurdod Gwasanaethau Busnes y GIG*”) means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(14);

“NHS pharmacist” (“*fferyllydd GIG*”) means—

- (a) a registered pharmacist, or
- (b) person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(15),

whose name is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;

“NHS services” (“*gwasanaethau GIG*”) means services provided as part of the health service in Wales;

“non-electronic prescription form” (“*ffurflen bresgripsiwn anelectronig*”) means a prescription form which falls within paragraph (a) of the definition of a “prescription form”;

“non-electronic repeatable prescription” (“*presgripsiwn amlroddadwy anelectronig*”) means a prescription which falls within paragraph (a)(i) of the definition of “repeatable prescription”;

“non-proprietary name” (“*enw amherchnogol*”) means a name which is, or which is a permitted variation of—

- (a) an International Nonproprietary Name (INN),
- (b) an International Nonproprietary Name Modified (INNМ),
- (c) a British Approved Name (BAN),
- (d) a British Approved Name Modified (BANM), or
- (e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published by the British Pharmacopoeia Commission and which has not been superseded(16);

“notice” (“*hybysiad*”) means a notice in writing;

“nurse independent prescriber” (“*nyrs-ragnodydd annibynnol*”) means a person—

- (a) whose name is registered in the Nursing and Midwifery Register,
- (b) against whose name in that register is recorded an annotation or entry signifying that they are qualified to order drugs, medicines and appliances as—
 - (i) a nurse independent prescriber, or
 - (ii) a nurse independent/supplementary prescriber, and

who, in respect of a person practising in Wales on or after 19 July 2010, has passed an accredited course to practise as a nurse independent prescriber;

(14) S.I. 2005/2414, amended by S.I. 2006/632, S.I. 2007/1201, S.I. 2013/235, S.I. 2015/1862, S.I. 2017/959 and S.I. 2018/378.

(15) 1968 c. 67.

(16) The British Pharmacopoeia 2020 is the leading collection of standards for UK medicinal products and pharmaceutical substances and is available at www.pharmacopoeia.com.

“Nursing and Midwifery Register” (“*Cofrestr Nyrsio a Bydwreigiaeth*”) means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(17) (establishment and maintenance of register);

“optometrist independent prescriber” (“*optometrydd-ragnodydd annibynnol*”) means a person—

- (a) who is an optometrist registered in the register of optometrists maintained under section 7 of the Opticians Act 1989(18) (which relates to the register of optometrists and the register of dispensing opticians) or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act, and
- (b) against whose name is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

“originating events” (“*digwyddiadau cychwynnol*”) means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;

“outline consent” (“*cydsyniad amlinellol*”) has the meaning given to it in regulation 30(1)(a) (outline consent and premises approval);

“outstanding pharmacy application” (“*cais am fferyllfa yn yr arfaeth*”) has the meaning given to it in regulation 31(11) (taking effect of outline consent and premises approval);

“paramedic independent prescriber” (“*parafeddyg-ragnodydd annibynnol*”) means a person—

- (a) who is registered as a paramedic in Part 8 of the Health and Care Professions Council register, and
- (b) against whose name is recorded in Part 8 of that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;

“patient list” (“ *rhestr cleifion*”) means a list of patients kept in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations or in respect of an APMS contractor or an LHBMS practice, in accordance with directions given by the Welsh Ministers under section 12(3) of the 2006 Act;

“pharmaceutical discipline committee” (“*pwylgor disgyblu fferyllol*”) has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(19);

“pharmaceutical list” (“ *rhestr fferyllol*”) means a list that a Local Health Board is required to prepare and maintain under regulation 10 (preparation and maintenance of pharmaceutical lists);

“pharmaceutical services” (“*gwasanaethau fferyllol*”) means pharmaceutical services that fall within sections 80 and 81 of the 2006 Act and includes directed services;

“pharmacist independent prescriber” (“*fferylllydd-ragnodydd annibynnol*”) means a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(20) (which relates to registers and the registrar) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

“pharmacy” (“*fferyllfa*”) means—

(17) S.I. 2002/253, amended by S.I. 2009/1182 and S.I. 2018/838.

(18) 1989 c. 44, amended by S.I. 2005/848.

(19) S.I. 1992/664. The definition of “pharmaceutical discipline Committee” was inserted by S.I. 1996/703.

(20) S.I. 1976/1213 (N.I. 22).

- (a) listed premises under regulation 10 (preparation and maintenance of pharmaceutical lists) at which pharmaceutical services are provided by an NHS pharmacist pursuant to arrangements made to section 80 of the 2006 Act, or
- (b) premises where under a pharmacy pilot scheme under section 92 of the 2006 Act (pilot schemes) the range of pharmaceutical services and the hours on which they are provided are comparable to a pharmacy falling within paragraph (a);

“physiotherapist independent prescriber” (*“ffisiotherapydd-ragnodydd annibynnol”*) means a person—

- (a) who is a physiotherapist, and
- (b) against whose name in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2002(21) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

“pilot scheme” (*“cynllun peilot”*) has the same meaning as in section 92(2) of the 2006 Act (pilot schemes);

“podiatrist or chiropodist independent prescriber” (*“podiatrydd-ragnodydd neu giropodydd-ragnodydd annibynnol”*) means a person—

- (a) who is a podiatrist or a chiropodist, and
- (b) against whose name in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2002 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

“practice premises” (*“mangre practis”*), in relation to a provider of primary medical services, means the address or addresses specified in the contract (in the case of a GMS or APMS contractor) or practice statement (in the case of an LHBMS practice) at which pharmaceutical services are to be provided under the contract or practice statement;

“preliminary consent” (*“cydsyniad rhagarweiniol”*) has the meaning given to it in regulation 18 (applications for preliminary consent and effect of preliminary consent);

“premises approval” (*“cymeradwyaeth mangre”*) has the meaning given to it in regulation 30(1)(b) (outline consent and premises approval) and includes temporary premises approval granted under regulation 34(13) (premises approval: additional and new premises after outline consent has taken effect) or residual premises approval granted under regulation 35(9) (premises approval: practice amalgamations);

“prescriber” (*“rhagnodydd”*) means a doctor, dentist, pharmacist independent prescriber, independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist or chiropodist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or a supplementary prescriber;

“prescription form” (*“ffurflen bresgripsiwn”*) means—

- (a) a form provided by a Local Health Board, an NHS Trust, an NHS Foundation Trust or an equivalent body and issued by a prescriber, or
- (b) an electronic prescription form,

that enables a person to obtain pharmaceutical services and does not include a repeatable prescription;

(21) S.I. 2002/254, amended by S.I. 2009/1182.

“Prescription of Drugs Regulations” (“*Rheoliadau Rhagnodi Cyffuriau*”) means the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(22);

“provider of primary medical services” (“*darparwr gwasanaethau meddygol sylfaenol*”) means a GMS contractor, APMS contractor or an LHBMS practice;

“Regional Partnership Board” (“*Bwrdd Partneriaeth Rhanbarthol*”) has the meaning given to it in regulation 1(4) of the Partnership Arrangements (Wales) Regulations 2015(23);

“registered pharmacist” (“*fferyllydd cofrestredig*”) means a person who is registered in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

“registered radiographer” (“*radiograffydd cofrestredig*”) means a person registered in Part 11 of the Health and Care Professions Council register;

“relevant APMS contractor” (“*contractwr GMDda perthnasol*”), in relation to any doctor, means—

- (a) the APMS contractor, where the doctor is an APMS contractor, or
- (b) where the doctor is not the APMS contractor, the APMS contractor by whom the doctor is employed or engaged;

“relevant European State” (“*Gwladwriaeth Ewropeaidd perthnasol*”) means an EEA State or Switzerland;

“relevant GMS contractor” (“*contractwr GMC perthnasol*”), in relation to any doctor, means—

- (a) the GMS contractor, where the doctor is a GMS contractor, or
- (b) where the doctor is not a GMS contractor, the GMS contractor by whom the doctor is employed or engaged;

“relevant list” (“*rhestr berthnasol*”) means—

- (a) a pharmaceutical list or an equivalent list, or
- (b) a list maintained by a Local Health Board or an equivalent body of approved performers or providers of primary medical, dental or ophthalmic services;

“relevant patient list” (“*rhestr cleifion berthnasol*”) means—

- (a) in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or APMS contractor, the patient list for that contractor, or
- (b) where the doctor is not a contractor, the patient list for the GMS contractor or APMS contractor by whom the doctor is employed or engaged or for the LHBMS practice within which the doctor provides primary medical services;

“relevant pharmaceutical needs assessment” (“*asesiad perthnasol o anghenion fferyllof*”) means the pharmaceutical needs assessment of the relevant Local Health Board that is current at the time that the Local Health Board takes its decision to grant or refuse an application, unless in the opinion of the Local Health Board (or on appeal the Welsh Ministers) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment;

“Remission of Charges Regulations” (“*Rheoliadau Peidio â Chodi Tâl*”) means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007(24);

(22) S.I. 2004/1022 (W. 119), amended by S.I. 2005/366 (W. 32), S.I. 2009/1838 (W. 166), S.I. 2009/1977 (W. 176), S.I. 2012/1916, S.I. 2013/683 (W. 81), S.I. 2014/109 (W. 09) and S.I. 2016/90 (W. 43).

(23) S.I. 2015/1989 (W. 299), amended by S.I. 2019/760 (W. 143).

(24) S.I. 2007/1104 (W. 116), amended by S.I. 2008/1480 (W. 153), S.I. 2008/2568 (W. 226), S.I. 2009/54 (W. 18), S.I. 2009/709 (W. 61), S.I. 2009/1824 (W. 165), S.I. 2009/2365 (W. 193), S.I. 2010/1237 (W. 107), S.I. 2010/2759 (W. 231), S.I. 2011/681

“repeat dispensing services” (“*gwasanaethau amlweinyddu*”) means pharmaceutical services which involve the provision of drugs or appliances by an NHS pharmacist or an NHS appliance contractor in accordance with a repeatable prescription;

“repeatable prescriber” (“*rhagnodydd amlroddadwy*”) means a person who is—

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 (repeatable prescribing services) of Schedule 6 to the GMS Regulations,
- (b) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations, or
- (c) employed or engaged by—
 - (i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations,
 - (ii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations, or
 - (iii) a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing services in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to LHBMS which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations;

“repeatable prescription” (“*presgripsiwn amlroddadwy*”) means a prescription contained in a form provided by a Local Health Board which—

- (a) is either—
 - (i) generated by computer but signed by a repeatable prescriber, or
 - (ii) a form created in an electronic format, identified using a repeatable prescriber’s code, transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service and is signed with a repeatable prescriber’s advanced electronic signature,
- (b) is issued or created to enable a person to obtain pharmaceutical services, and
- (c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

“reserved location” (“*leoliad neilltuedig*”) has the meaning given to it by regulation 17(4) (locations in controlled localities that are reserved locations);

“restricted availability appliance” (“*cyfarpar argaeledd cyfyngedig*”) means an appliance which is approved for particular categories of persons or particular purposes only;

“Scheduled drug” (“*cyffur Atodlen*”) means a drug or other substance specified in Schedule 1 or 2 to the Prescription of Drugs Regulations (which relate to drugs, medicines and other substances not to be ordered under a general medical services contract or that may be ordered only in certain circumstances);

“serious shortage protocol” (“*protocol prinder difrifol*”) means—

- (a) in the case of a prescription only medicine, a serious shortage protocol for the purposes of regulation 226A of the Human Medicines Regulations 2012⁽²⁵⁾ (sale etc. by a pharmacist in accordance with a serious shortage protocol), or
- (b) in the case of any other drug or appliance, a written protocol that—
 - (i) is issued by the Welsh Ministers in circumstances where Wales or any part of Wales is, in the opinion of the Welsh Ministers, experiencing or may experience a serious shortage of—
 - (aa) a specified drug or appliance, or
 - (bb) drugs or appliances of a specified description,
 - (ii) provides for the supply by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical or local pharmaceutical services, where there is an order on a prescription form or a repeatable prescription for—
 - (aa) the specified drug or appliance, or
 - (bb) a drug or appliance of the specified description,
of a different product or quantity of product to the product or quantity of product ordered, subject to such conditions as may be specified in the protocol, and
 - (iii) specifies the period for which, and the parts of Wales (which may be all of Wales) in which, the protocol is to have effect;

“signatory” (“*llofnodwr*”) means a natural person who creates an electronic signature;

“specified appliance” (“*cyfarpar penodedig*”) means—

- (a) any of the following appliances listed in Part IXA of the Drug Tariff—
 - (i) a catheter appliance (including a catheter accessory and maintenance solution),
 - (ii) a laryngectomy or tracheostomy appliance,
 - (iii) an anal irrigation system,
 - (iv) a vacuum pump or constrictor ring for erectile dysfunction, or
 - (v) a wound drainage pouch,
- (b) an incontinence appliance listed in Part IXB of the Drug Tariff, or
- (c) a stoma appliance listed in Part IXC of the Drug Tariff;

“stoma appliance customisation” (“*addasu cyfarpar stoma*”) means the customisation of a quantity of more than one stoma appliance, where—

- (a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff,
- (b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance, and
- (c) that modification is based on the patient’s measurements or a record of those measurements and, if applicable, a template;

“SSP” (“*PPD*”) means a serious shortage protocol;

“superintendent” (“*uwcharolygydd*”) has the same meaning as in section 71 of the Medicines Act 1968⁽²⁶⁾ (bodies corporate);

⁽²⁵⁾ S.I. 2012/1916; regulation 226A was inserted by S.I. 2019/62.

⁽²⁶⁾ Section 71 was substituted by section 28 of the Health Act 2006 (c. 28).

“supplementary opening hours” (“*oriau agor atodol*”) is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 5 or paragraph 13(3)(a) of Schedule 6, or both;

“supplementary prescriber” (“*rhagnodydd atodol*”) means—

- (a) a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber,
- (b) a person whose name is registered in the Nursing and Midwifery Register and against whose name in that Register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a nurse independent/supplementary prescriber,
- (c) a person—
 - (i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001(27) (establishment and maintenance of register) which relates to chiropodists and podiatrists, dieticians, paramedics, physiotherapists or radiographers, and
 - (ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber, or
- (d) an optometrist against whose name in the register of optometrists maintained under section 7 or 8B(1)(a) of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as a supplementary prescriber;

“therapeutic radiographer independent prescriber” (“*radiograffydd therapiwtig-ragnodydd annibynnol*”) means a person—

- (a) who is a registered radiographer, and
- (b) against whose name is recorded in Part 11 of the Health and Care Professions Council register—
 - (i) an entitlement to use the title “therapeutic radiographer”, and
 - (ii) an annotation signifying that they are qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;

“Tribunal” (“*Tribiwnlys*”) means the First-tier Tribunal established under the Tribunals, Courts and Enforcement Act 2007(28).

(2) Where reference is made in these Regulations to a decision of a Local Health Board and that decision is changed on appeal, unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision changed on appeal.

(3) In these Regulations—

- (a) the term “pharmaceutical services”, in the context of arrangements for the provision of pharmaceutical services by a doctor, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 86(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services), and
- (b) the term “dispensing services”, in relation to a doctor or GMS contractor, means any corresponding service provided, not as pharmaceutical services, but under the terms of

(27) S.I. 2002/254. Article 5 has been amended by S.I. 2009/1182. The Order was renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).

(28) 2007 c. 15.

a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations.

(4) Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations may be given or sent by delivering it to the person or, in the case of a body, to the secretary or general manager of that body, or by sending it in a prepaid letter addressed to that person or, in the case of a body, to the secretary or general manager of that body at his usual or last known address, and delivering it includes sending it electronically to an electronic address which that person has notified for the purpose.

(5) Where the term “community practitioner nurse prescriber” appears in the Human Medicines Regulations 2012⁽²⁹⁾ or the Nursing and Midwifery Register it is to be construed for the purposes of these Regulations as a reference to an “independent nurse prescriber”.

⁽²⁹⁾ S.I. 2012/1916, amended by S.I. 2013/235, S.I. 2013/1855, S.I. 2013/2593, S.I. 2014/490, S.I. 2014/1878, S.I. 2015/323, S.I. 2015/903, S.I. 2015/1503, S.I. 2015/1862, S.I. 2015/1879, S.I. 2016/186, S.I. 2016/190, S.I. 2016/696, S.I. 2017/715, S.I. 2017/1322, S.I. 2018/199, S.I. 2018/378 and S.I. 2019/62.